

REMARKS

Claims 7-10 and 12-15 are pending. Claims 7 and 12 have been amended. Amendments to claims 7 and 12 were done merely to clarify the claims and correct antecedent basis issues pointed out by the Examiner. Therefore, no new matter has been added. Reconsideration of the present application is requested in view of the following remarks.

I. Withdrawal of Prior Rejections

Applicant acknowledges with appreciation the withdrawal of prior rejections.

II. Oath or Declaration

The Examiner indicated that the Oath or Declaration was defective. A new Oath or Declaration is provided, herewith.

III. Trademarks

The Examiner objected the specifications for improper use of trademarks. Applicant has amended the specification to correct the format of trademarks. However, Applicant would like to note that “Mimotope” does not appear to be a trademark. Applicant requests that objections relating to the format of certain trademarks be withdrawn in view of the current amendments to the specification.

IV. Rejection Under 35 U.S.C. § 112, First Paragraph – Written Description

Claims 7-9 and 12-14 are rejected under 35 U.S.C. § 112, first paragraph for allegedly failing to comply with the written description requirement. Applicant respectfully traverses because the claims are described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, at the time the application was filed, had possession of the claimed invention.

MPEP 2163(II)(A)(3) provides that an adequate written description may be shown by any description of sufficient, relevant, identifying characteristics so long as the artisan would recognize that the inventor had possession. The written description requirement for a claimed genus may be satisfied, for example, by disclosure of relevant, identifying characteristics, i.e.,

structure or other physical and/or chemical properties, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession.

Moreover, description of a representative number of species does not require the description to be of such specificity that it would provide individual support for each species that the genus embraces. Satisfactory disclosure of a "representative number" depends on whether the artisan would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed. Based on these principles, Applicant submits that the presently pending claims meet the written description requirement.

Claims 7 and 12 are directed to methods of reducing the immunogenicity or allergenicity of a bone morphogenetic protein by modifying a T-cell epitope of the bone morphogenetic protein to produce a variant protein, where the amino acid sequence of the T-cell epitope is selected from the group consisting of SEQ ID NO:1-8. The Examiner alleges that the specification does not disclose a representative number of BMP proteins that comprise at least one of SEQ ID NO:1-5 that are not BMP-7 and as a result the instant specification does not adequately breadth of bone morphogenic protein in the claimed methods. This argument is without merit as one of ordinary skill in the art at the time of filing could have easily figure out which bone morphogenetic proteins comprise SEQ ID NO:1-8.

The sequence of bone morphogenetic proteins were known in the art before the application was filed. Thus the disclosure of SEQ ID NO:1-8 combined with the pre-existing knowledge in the art regarding amino acid sequences of bone morphogenetic proteins would have put one in possession of the genus of a bone morphogenetic protein comprising a T-cell epitope of an amino acid sequence selected from the group of SEQ ID NO:1-8. With the aid of a computer, for example, one of ordinary skill in the art could have identified all the bone morphogenetic protein comprising a T-cell epitope of an amino acid sequence selected from the group of SEQ ID NO:1-8.

Thus one of ordinary skill in the art would conclude that the applicant was in possession of the claimed genus at the time of the application. Withdrawal of this rejection is respectfully requested.

V. **Rejection Under 35 U.S.C. § 112, First Paragraph – Enablement**

Claims 7-9 and 12-14 are rejected under 35 U.S.C. § 112, first paragraph as allegedly failing to comply with the enablement requirement. Applicant respectfully traverses because the specification clearly teaches how to make and use the claimed invention without undue experimentation.

According to MPEP 2164.02, compliance with the enablement requirement of 35 U.S.C. § 112, first paragraph, requires that the information contained in the disclosure of an application must be sufficient to inform those skilled in the relevant art how to both make and use the claimed invention. Detailed procedures for making and using the invention may not be necessary if the description of the invention itself is sufficient to permit those skilled in the art to make and use the invention without undue experimentation.

Claims 7 and 12 are directed to methods of reducing the immunogenicity or allergenicity of a bone morphogenetic protein by modifying a T-cell epitope of the bone morphogenetic protein to produce a variant protein, where the amino acid sequence of the T-cell epitope is selected from the group consisting of SEQ ID NO:1-8. As discussed above, one of ordinary skill in the art would be able to readily identify bone morphogenetic proteins comprising SEQ ID NO:1-8. Furthermore, the specification provides ample guidance on how to modify the amino acid sequences of the T-cell epitopes (See, for example, paragraphs [0072], [0073]). Methods of modifying amino acid sequences are also well known in the art. The specification also provides ample support on how to test the variant proteins for immunogenicity or allergenicity (See, for example, paragraphs [0123]-[0127] and Examples). Furthermore, there would be no undue burden for the skilled person to make and test variants. This would require merely minor adaptations of the teaching found in Examples of the present application to screen a finite number of variants.

The claimed invention is described in the specification in such a way as to enable one skilled in the art to make and/or use the invention. Withdrawal of this rejection is respectfully requested.

VI. **Rejection Under 35 U.S.C. § 112, Second Paragraph**

Claims 7-10 and 12-15 are rejected under 35 U.S.C. § 112, first paragraph. Applicant respectfully traverse but in order to expedite prosecution, without acquiescing to Examiner's rejection, Applicant has opted to amend the claims per Examiner's suggestion. Withdrawal of this rejection is respectfully requested in view of the current claim amendments.

CONCLUSION

Applicant believes the present application is in condition for allowance. If a telephone conference would expedite allowance of this application, the Examiner is invited to telephone the undersigned at (650) 846-7639. The Commissioner is authorized to charge any fees that may be required in connection with this submission and to credit any overpayments to Deposit Account No. 07-1048 (Docket No. GC818-US).

Respectfully submitted,

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